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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/653,325 | 09/02/2003 | Allan H. Graff | C75128-1 | 2971 |

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GLAXOSMITHKLINE

Corporate Intellectual Property - UW2220

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/653,325 | Applicant(s) GRAFF ET AL. | |
| | Examiner Blessing M. Fubara | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/20/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of response to Notice to File Missing Parts filed 12/02/03/02 and IDS filed 10/20/03.

Priority

Examiner acknowledges this application as a continuation-in-part of application serial number 10/244,782 that is filed 09/16/02.

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner cited the references on form PTO-892, they have not been considered.

Drawings

The section on the "brief description of the drawing" is missing. Correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe that by derivatives of nicotine, we mean ... or that nicotine derivatives are Question: Could it be that derivatives of nicotine meeting the intent of the invention are nicotine oil, nicotine bitartrate and nicotine polacrilex? If the response were yes, examiner would suggest removing derivatives of nicotine from the claim. The specification does not say that derivatives of nicotine are

5. Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 16 recites the limitation "the nicotine active" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not provide antecedence for nicotine active.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 6-8, 32 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Ream et al. (US 6,290,985).

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Ream discloses composition that comprises nicotine (column 8, line 58; column 9, line 6), guar gum hydrolysate (column 12, lines 62 and 63) and isomalt (column 7, line 49). Claims 32 and 33 recite future intended use of nicotine containing composition and future intended use is not critical in a composition claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ventouras (US 6,183,775 B1) in view of Rapp et al. (US 6,180,143 B1) or Bunick et al. (US 2003/0017202 A1).

Ventouras discloses controlled release lozenge that contains soluble filler namely maltitol, xylitol, sorbitol, mannitol, lactose, dextrose, saccharose, fructose and any mixture (column 1, lines 53 and 65-67; column 2, lines 1-8), insoluble film forming agent namely acrylates, EUDRAGIT, polyvinylpyrrolidone, cellulose acetate, shellac and cellulose acetate phthalate (column 2, lines 13-43), swellable polymer namely xanthan gum, guar gum, alginate and polysaccharides (column 2, lines 48-59), active agent such as nicotine tartrate, nicotine polacrilex and nicotine (column 3, lines 5-30) and auxiliaries that can be lubricants, flavors, aromas, sweeteners, buffering agents and glidants (column 3, lines 31-35). Specifically, nicotine formulation of Ventouras contains sodium carbonate or sodium bicarbonate (formulas 1-5). While Ventouras discloses nicotine formulations containing sweeteners such as aspartame,

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saccharine, the formulation of Ventouras does not contain non-hygroscopic sugar alcohol as sweetener. However, Rapp discloses nicotine formulation that contains a sweetening agent mixture of 1,6-GPS, 1,1-GPS and 1,1-GPM (abstract; column 4, lines 38-67). Also, Bunick discloses formulation that contains nicotine, isomalt and xanthan gum (abstract; paragraph [002]; paragraph [0012]; paragraph [0015]).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine lozenge as disclosed by Ventouras. One having ordinary skill in the art would have been motivated to include as an auxiliary a sweetener that is known in the art to be formulated with nicotine according to Rapp or Bunick with the expectation of imparting low hygroscopy to the lozenge and that sweetener is isomalt, a mixture or 1,6-GPS and 1,1-GPM.

11. Claims 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ream et al. (US 6,290,985).

Ream is described above. Ream does not disclose the amount of the gum. However, differences in amounts or concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such amount or concentration is critical. And “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine composition of Ream and use the desired amounts of gum and active nicotine with the expectation of delivering nicotine to an individual.

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Double Patenting

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-33 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-33 of copending Application No. 10/244,782. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

15. Claim 33 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 52 of copending Application No. 10/471,477. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

16. Claims 1, 3 and 13-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 28-39 of

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compending Application No. 10/471,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claim 1 is directed to a broad active agent that is further defined by claim 3 as nicotine. Claim 1 of the co-pending application is directed to a nicotine active. The nicotine formulation in the dependent claims of the co-pending application further includes buffering agents. The co-pending claims do not contain gelling gum as is directed by the examined claims. However, it is known in the art and disclosed by Ream that nicotine can be formulated with guar gum and isomalt (column 12, lines 62 and 63; column 7, line 49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include gelling gum to the nicotine formulation of the co-pending claims with the expectation of having a nicotine product having the desired structure and consistency.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dam et al. (US 5,733,574) discloses nicotine formulation that comprises buffering agents, gelling agents, flavoring agents, coloring agents, vitamins and minerals and stabilizing additives (abstract, columns 3-9).

Durr et al. (US 6,139,864) discloses nicotine formulation having 1,6-GPS and 1,1-GPM sugar alcohol (columns 3 and 4).

Getz et al. (US 6,270,804) discloses bio-affecting sachet formulations containing nicotine (column 4, line 45) and isomalt carrier (column 6, lines 52-62).

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Santus (US 6,280,761) discloses lozenge formulation containing nicotine (column 4, lines 19-44), buffering agents (column 8, lines 20-27), non-nutritive sweetener (column 6, lines 42-51), and absorbent excipient (column 6, lines 9-41).

19. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

